UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its "Report of FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for chlorpropham". A Notice of Availability, allowing public comment for a 30-day period, will be published in the *Federal Register* (FR) shortly. This TRED, which was approved on July 19, 2002, contains the Agency's decision on chlorpropham.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the Food Quality Protection Act (FQPA) in August of 1996 against the new safety standard adopted in the FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a modification or revocation occurs. A reregistration eligibility decision (RED) for chlorpropham, was finalized and signed on August 1, 1996, prior to FQPA enactment**.** Therefore, it needed to be updated to reassess the tolerances under the FQPA standard.

The Agency has evaluated the dietary risk associated with chlorpropham and has determined that provided the Special Local Need registration (SLN) for Easter lily bulb use is amended to reduce the maximum rate of application from 3.99 lb a.i./A to 2.0 lb a.i./A as agreed upon by stakeholders, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to chlorpropham when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, with this mitigation measure in place, 15 tolerances are now considered reassessed and 9 new tolerances are will be established for residues of chlorpropham in/on raw agricultural commodities under section 408(q) of the FFDCA.

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually. EPA did not perform a cumulative risk assessment as part of this reregistration review of chlorpropham, because the Agency has not determined if there are any other chemical substances that have a mechanism of toxicity common with that of chlorpropham. If EPA identifies other substances that share a common mechanism of toxicity with chlorpropham, then a cumulative risk assessment will be conducted that includes chlorpropham. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Chlorpropham will be reevaluated at that time and additional studies may be required.

The Agency's human health findings for the pesticide chlorpropham, were discussed in a closure conference call, and are summarized in the enclosed chemical overview of the risk assessments. These risk assessments and other documents pertaining to the chlorpropham tolerance reassessment decision are listed at the end of this document (Attachment 1) and are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and in the public docket for viewing.

Tolerances are established for residues of chlorpropham in/on raw agricultural commodities as defined in 40 CFR §180.181. The current tolerance in or on potatoes is currently expressed in terms of the combined residues of chlorpropham and its 1-hydroxy-2-propyl-3'-chlorocarbanilate metabolite and is established at 50 parts per million (ppm). The tolerance for potatoes should be reduced to 30 ppm, and be expressed in terms of chlorpropham alone (chlorpropham *per se*). Additionally, a tolerance for residues of chlorpropham on potatoes, wet peel, should be established at 40 ppm.

Interim tolerances have been established for residues of chlorpropham in/on plant and animal commodities in 40 CFR §180.319. The Agency will propose to reassess thirteen interim tolerances including milk, meat, fat, and meat byproducts of cattle, hog, horse, and sheep, based on results of the ruminant feeding study, and will propose to revoke one interim tolerance (spinach) for failure to provide additional data required to support reregistration. Tolerances will be raised or established to express combined residues of chlorpropham and 4-HSA (4-hydroxychlorpropham-O-sulfonic acid) for the meat and meat byproducts of cattle, horse, sheep, goat, and hog at 0.06 ppm (except kidney), 0.30 ppm for kidney and milk, and 0.20 ppm for fat (a total of 21 tolerances). A total of 24 tolerances will be raised, established, or revoked by the TRED for chlorpropham when the tolerances for post-harvest and wet peel potato are included, and the revocation for spinach occurs.

The Codex Commission has not established or proposed maximum residue limits (MRLs) for residues of chlorpropham in/on various raw agricultural and processed commodities. Therefore, there are no inconsistencies with respect to compatibility of U.S. tolerances with Codex MRLs. The following table summarizes EPA's tolerance reassessment decision.

Table 1. Tolerance Reassessment Summary for Chlorpropham

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Current and Proposed Tolerances Under 40 CFR § 180.181 for chlorpropham *per se*			
Potato (Post-Harvest)	50	30	Tolerance lowered based on results of a magnitude of residue study in potatoes for chlorpropham *per se*. Currently listed under 40 CFR § 180.181 as combined residues of chlorpropham and its 1-hydroxy-2-propyl-3'- chlorocarbanilate metabolite.
Potato, wet peel	none	40	Tolerance to be established based on field trial and commercial-scale processed potato waste studies. This tolerance is based on the Highest Average Field Trial (HAFT), the maximum expected residue in potato, wet peel, at 36 ppm, and the average concentration factor (3x) from a commercial-scale processed potato waste study.
Interim Tolerances Currently Listed Under 40 CFR § 180.319 for chlorpropham *per se* and Proposed Reassessed Tolerances			
Cattle, meat	0.05	0.06	Tolerance raised (or established) based on results of a ruminant feeding study and calculated Maximum Theoretical Dietary Burden (MTDB) estimates. The current tolerance should be recodified under 40 CFR §180.181(a) (1) to be expressed for combined residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA).
Cattle, fat	0.05	0.20	
Cattle, kidney	none	0.30	
Cattle, meat byproduct[1]	0.05	0.06	
Hog, meat	0.05	0.06	
Hog, fat	0.05	0.20	
Hog, Kidney	none	0.30	
Hog, meat byproducts[1]	0.05	0.06	
Goat, meat	none	0.06	
Goat, fat	none	0.20	
Goat, kidney	none	0.30	
Goat, meat byproducts[1]	none	0.06	
Horse, meat	0.05	0.06	
Horse, fat	0.05	0.20	
Horse, kidney	none	0.30	
Horse, meat byproducts[1]	0.05	0.06	
Milk	0.05	0.30	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Sheep, meat	0.05	0.06	Tolerance raised (or established) based on results of a ruminant feeding study and calculated Maximum Theoretical Dietary Burden (MTDB) estimates. The current tolerance should be recodified under 40 CFR §180.181(a) (1) to be expressed for combined residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA).
Sheep, fat	0.05	0.20	
Sheep, kidney	none	0.30	
Sheep, meat byproducts[1]	0.05	0.06	
Spinach	0.3	Revoke	The interim tolerance was based on insufficient data; proposed revocation is based on failure to provide additional data required to support tolerance reassessment

[1] Revised Commodity Definition: (except kidney)

Labeling For End-Use Products

In completing this TRED, the Agency has identified certain label amendments which should be implemented. A tabular summary of label amendments, listed below, describes how label language should be amended. The implementation of these amendments will ensure that the reassessed tolerances are adequate for the maximum label rates, and will also ensure consistency among the labels.

In order to be eligible for reregistration, registrants supporting chlorpropham registrations must submit label applications for amended registration. This application should include the following items: a completed EPA application form 8570-1, five copies of the draft label with all label amendments outlined in Table 2 of this document incorporated, and a description on the application, such as, "Responding to TRED Document". All amended labels need to be submitted within 8 months of signature of this document to the Registration Division (RD). The RD contact is Cynthia Giles-Parker at (703) 305-7740.

Table 2. Amendments to CIPC Labels based on Formulation Class

Formulation Class	Recommended Label Amendments
Aerosol Ready To Use (RTU) Products	The product labels currently state that "if potatoes are held in storage longer than originally anticipated, the potatoes may be retreated." The labels should clearly state a total seasonal rate of 0.028 lb ai/1000 lbs potatoes, not to exceed 165% of the typical (0.017lb ai/1000lbs of potatoes) rate. In the case of labels specifying 145% of the typical rate, the total seasonal rate should not exceed 0.025lbs ai/1000lbs of potatoes.
For all products heated above 250E F, including CIPC Briquette Aerosol (EPA Reg. Number 2749-520), and Pin Nip 98.6% Aerosol (EPA Reg. Number 65726-3)	For entry into the enclosed treatment/storage area anytime after application until ventilation requirements listed on this labeling have been completed, in addition to PPE (long-sleeved shirt and long pants; shoes plus socks; chemical resistant gloves such as or made of any waterproof material); handlers must wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any R, P prefilter
Emulsifiable Concentrate (EC)	Label should be amended to reduce the maximum rate of application from 3.99 lb a.i. to 2.0 lb a.i. per acre for Easter lily use For potatoes, a maximum seasonal rate (0.0104 lb ai/1000lbs potatoes) should be specified.

Additional Generic Data Requirements

Additional generic confirmatory data are required concerning UV/Visible Absorption (OPPTS 830.7050) for technical registrants of chlorpropham.

The Agency is also requesting a special residue study (under crop field trial guideline study, OPPTS 860.1500) to determine the potential for thermal degradates to form during aerosol application as a result of thermal degradation to deposit as residues in or on stored potatoes. The study is required because the Agency cannot determine whether or not the chlorophenyl isocyanate, or other thermal degradates, are produced during aerosol treatment based on the literature citations and the submitted plant metabolism study alone. The study should include the range of temperatures typically used by the aerosol generators, at what temperature the decomposition products are formed during the process and the presence and amount of any isocyanates; (in particular, chlorophenyl isoncyanate), as well as the potential intermediary 5-chloro-2-benzoxazolinone.

Note that Technical registrants will be sent a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(2)(B) Data-Call-In (DCI) letter in a separate mailing. If

you have questions on this document, please contact the Chemical Review Manager, Gary Mullins, at (703) 308-8044.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

2 Enclosures: Chlorpropham Summary and Overview

ATTACHMENT 1

Supporting Documents Considered for the Chlorpropham Tolerance Reassessment Decision

1. Danette Drew (USEPA\OPPTS\OPP\HED).Chlorpropham (CIPC) (018301). HED's Revised Human Health Risk Assessment Chapter for the Tolerance Reassessment Eligibility Decision. July 10, 2002.

2. Danette Drew (USEPA\OPPTS\OPP\HED).Chlorpropham (CIPC) (018301).Revised Product Chemistry and Residue Chemistry Chapter for the Tolerance Reassessment Eligibility Decision (TRED). June 10, 2002.

3. Danette Drew (USEPA\OPPTS\OPP\HED). Chlorpropham (CIPC) (018301).Acute, Chronic and Cancer Anticipated Residues and Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision. February 25, 2002.

4. William B. Greear (USEPA\OPPTS\OPP\HED).Chlorpropham - Reregistration Case No. 0271 - Toxicology Chapter for the Reregistration Eligibility Decision Document on Chlorpropham. January 13, 1999.

5. Brenda Tarplee (USEPA\OPPTS\OPP\HED).Report of the FQPA Safety Factor Committee. December 17, 1998.

6. Dirk F. Young, Ph.D., (USEPA\OPPTS\OPP\EFED). Revised FQPA Drinking Water Assessment for Chlorpropham. June 3, 2002.

7. Danette Drew, (USEPA\OPPTS\OPP\HED). Response to Registrant's Letter Regarding Label Amendments. November 20, 2001.

8. David G. Anderson, Ph.D., (USEPA\OPPTS\OPP\HED). Carcinogenicity Peer Review of Chlorpropham October 11, 1994.

9. Danette Drew, (USEPA\OPPTS\OPP\HED). Response to CIPC Task Force Comments on the Human Health Risk Assessment for the TRED. March 27, 2002

10. Danette Drew, (USEPA\OPPTS\OPP\HED). Agency's Response to Pin Nip April 08, 2002 Comments on the Human Health Risk Assessment for the Tolerance Reassessment Eligibility Decision (TRED). April 11, 2002

11. Lori L. Brunsman (USEPA\OPPTS\OPP\HED). Para-Chloroaniline Hydrochloride (Diflubenzuron, Dimilin), (017203), Quantitative Risk Assessment (Q_1*) Based on $B6C3F_1$ Mouse Gavage Study With mg/kg Body Weight$^{3/4}$/Day Unterspecies Scaling Factor. June 14, 2001.

12. William B. Greear (USEPA\OPPTS\OPP\HED). Chlorpropham - Report of the Hazard Identification Review Committee. October 16, 1998.

These risk assessments and other documents pertaining to the chlorpropham tolerance reassessment decision are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm, and in the public docket for viewing.